



# Specification

1.00419.9025 Parteck® M 200 (Mannitol) EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,  
E 421

Specification		
Assay (HPLC, calc. on dried substance)	98.0 - 101.0	%
Identity (NIR)	passes test	
Appearance of solution (10 %; water)	passes test	
pH-value (10 %; water)	4.5 - 7.5	
Melting point	165 - 169	°C
Conductivity (25°C) (20 %; water)	≤ 20	μS/cm
Heavy metals (as Pb)	≤ 5	ppm
Ni (Nickel) (#)	≤ 1	ppm
Pb (Lead)	≤ 0.5	ppm
Related substances (HPLC) (Sorbitol (Impurity A))	≤ 2.0	%
Related substances (HPLC) (Sum of Maltitol and Isomalt (Impurities B and C))	≤ 2.0	%
Related substances (HPLC) (Major unspecified impurity)	≤ 0.10	%
Related substances (HPLC) (Sum of all impurities)	≤ 2.0	%
Reducing sugars (as glucose)	≤ 0.05	%
Reducing sugars after hydrolysis/total sugar (as glucose)	≤ 1	%
Sulfated ash	≤ 0.1	%
Water	≤ 0.5	%
Loss on Drying (105 °C)	≤ 0.30	%
Particle size (< 53 μm)	≤ 15	%
Particle size (> 500 μm)	≤ 15	%
Residual solvents (ICH Q3C)	excluded by manufacturing process	

Parameter with periodic testing

Microbiological test	passes test	
Colony count (aerobic bacteria (TAMC))	≤ 10 <sup>3</sup>	CFU/g
Colony count (Yeasts and moulds (TYMC))	≤ 10 <sup>2</sup>	CFU/g
Salmonella spp.	in 10g Substance not detectable	
E.coli	in 1g Substance not detectable	
Staphylococcus aureus	in 1g Substance not detectable	
Pseudomonas aeruginosa	in 1g Substance not detectable	

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Candida albicans In 1g Substance  
not detectable

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities).  
Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (#).  
Corresponds to Ph. Eur., BP, JP, USP, E 421  
Conforms to the purity criteria on food additives according to the current European Commission Regulation.

Jennifer Standare  
Responsible laboratory manager quality control

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